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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/055,663 | 01/23/2002 | Erik H.F. Wong | 28341/6248.8 | 7737 |

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EXAMINER

JARVIS, WILLIAM R A

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1614

DATE MAILED: 03/26/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/055,663

Applicant(s)

WONG ET AL.

Examiner

William R. Jarvis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-17,32-41,44-51 and 54-57 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) ☐ Claim(s) ____ is/are allowed.

6) ☒ Claim(s) 1-17,32-41,44-51 and 54-57 is/are rejected.

7) ☐ Claim(s) ____ is/are objected to.

8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2,4. 6) ☐ Other: ____.

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1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 38, 41, 44-51, 55, 57 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating incontinence, does not reasonably provide enablement for preventing incontinence. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. Since preventing a disease or condition is unexpected and requires significant experimentation to establish, applicant's claims relating to preventing incontinence are not enabled. Applicant's specification fails to provide clear evidence of the efficacy of selective norepinephrine inhibitors including reboxetine in preventing incontinence. Accordingly, the claims should be limited to treating incontinence.

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1-17, 32-41, 44-51, and 54-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's submitted references U.S. Patents 5,281,624 (to Gehlert et al) or 5,441,985 (to Foreman), each in view of Dostert et al. Gehlert teaches the use of certain selective and potent norepinephrine inhibitors for the treatment of urinary incontinence; see particularly col. 1, lines 34-68. Similarly, Foreman teaches the use of norepinephrine inhibitors for the treatment of urinary incontinence; see the abstract and the claims.

Applicant's claims differ in that they require a compound having a pharmacological selectivity of serotonin (K_i)/norepinephrine (K_i) of at least about 5000 (e.g. (S,S)-reboxetine. However, the secondary reference teaches that reboxetine is a selective norepinephrine reuptake inhibitor and that the (S,S) enantiomer is the more potent of the two. Since it was well-known at the time of applicant's invention that selective norepinephrine inhibitors were highly effective at treating urinary incontinence and that (S,S)-reboxetine is a potent selective norepinephrine inhibitor, one skilled in the art would have clearly motivated to treat urinary incontinence with (S,S)-reboxetine. Although the prior art does not specifically disclose a compound having a pharmacological selectivity of serotonin (K_i)/norepinephrine (K_i) of at least about 5000, this high selectivity is inherent in administering (S,S)-reboxetine to a patient. To treat particular types of incontinence with the claimed compounds is clearly obvious since the skilled artisan would expect success in treating subtypes of a disorder with the same drug. The claimed amounts or dosages are obvious since it is within the skill of the pharmaceutical artisan to determine the amount or dosage of a drug that provides the therapeutic effect most effective for

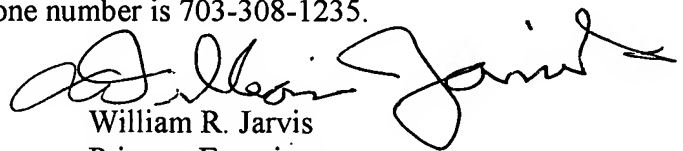
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treating the patient's condition while minimizing adverse side effects. The claimed modes of administration and the use of excipients and carriers are obvious since they are conventional to one skilled in the pharmaceutical arts.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to William R. Jarvis whose telephone number is 703-308-4613. The examiner can normally be reached on Monday, Tuesday, Thursday & Friday 7:00am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne C. Seidel can be reached on 703-308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.


William R. Jarvis
Primary Examiner
Art Unit 1614

wrj
March 23, 2003